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10/062,379	02/01/2002	Ronald A. Heddleson	5367USA	2577

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/062,379	Applicant(s) HEDDLESON ET AL.	
	Examiner Francisco C Prats	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-20 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 14-16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "short chain beta glucan" renders the claims indefinite. Because "short" is a relative term having an entirely subjective meaning, a glucan considered by one practitioner to be "short" will not necessarily be the same as a glucan considered to be "short" by another practitioner. The term "short" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is noted that applicant provides a definition for "short chain beta glucan" on page 8 of the specification. However,

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that section of the specification provides a series of consecutively narrowing "preferable" meanings for the term. This type of definition is improper because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In sum, only those claims containing actual empirical molecular weight values can be considered definite under 35 U.S.C. § 112, second paragraph.

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Claim 1 and its dependents are also considered indefinite because the claim does not clearly set forth the actual sequence of steps the practitioner must perform to fall within the claims. The sequence of steps is confusing, especially when viewed in light of the specification. Specifically, there is no claim language which links the first "obtaining" step to the subsequent "providing" and "adding" steps. The first step simply does not have any clear relationship to the second and third steps. Thus, according to the current claim language, the claimed process is practiced by obtaining a short chain beta glucan, and then combining a food product/intermediate with a modifying agent which may be an enzyme. The claim does not require the practitioner to do anything with the short chain beta glucan obtained in the first step.

Consulting the specification, it appears that the short chain beta glucan must be added to the food product/intermediate. However, the current claim language does not state when in the sequence of steps the glucan and enzyme are combined. Because the current claim language is unclear as to what must be done to practice the claimed invention, and when it must be done, a holding of indefiniteness is clearly required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen et al (U.S. Pat. 4,871,571).

Jensen discloses a glucanase-digested beta glucan bulking agent from barley, wherein over 80% of the molecular species are from DP₃ to DP₅. See Example 1, at column 8. Because the molecular weight of glucose is about 180 Da, the molecular weight of the various species is from about 540 Da to 900 Da, well within the claimed ranges. Thus, because it contains all of the claimed ingredients, the enzymatic digestion milieu of Jensen, for example in Example 1, anticipates product claim 10.

With respect to other product claims, it is noted that Jensen's glucan is prepared after amylase digestion of the barley. However, the glucan product resulting from Jensen's process is the same as one which would be produced from *in situ* glucanase digestion of the barley. Thus, in addition to claim

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10, Jensen must be considered to anticipate product claims 11-17. Moreover, Jensen discloses the use of the enzyme-digested glucan in edible products such as cookies. See Example 2, at columns 8 and 9.

With respect to the process claims, Jensen clearly provides a food product/intermediate, i.e. barley, and amylase-treated barley (see Example 1, at column 8), thereby meeting the second step required in claim 1. Jensen mixes the amylase-treated barley with beta glucanase, thereby adding to the food product at least one modifying agent, thus meeting the third step in the claim 1. The addition of the glucanase to the amylase-treated barley results in obtaining a short chain glucan having the claimed molecular weight, thus meeting the first required step in the claims. The addition of the glucanase to the amylase-treated barley also result in the preparation of the food product/intermediate, thus meeting the fourth step in the claims. A holding of anticipation over claim 1 and certain of its dependents is therefore also required.

Claims 1-3, 11, 14-16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al (U.S. Pat. 3,880,742).

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James discloses a process of rendering animal feed more digestible by adding beta glucanase directly, i.e. *in situ*, to barley-based animal feed. See, e.g., Example 5, at column 9. The addition of glucanase to the glucan necessarily results in "short" chain glucans, since the term "short" reads on virtually any digested glucan chain. Thus, the glucanase-digested glucan of James anticipates claim 11 and certain of its dependents.

With respect to the process claims, James clearly provides a food product/intermediate, e.g. barley-based chicken feed in Example 5, thereby meeting the second step required in claim 1. James mixes the barley-based with beta glucanase, thereby adding to the food product at least one modifying agent, thus meeting the third step in the claim 1. The addition of the glucanase to the barley-based chicken feed results in obtaining a short chain glucan, thus meeting the first required step in the claims. The addition of the glucanase to the barley-based chicken feed also results in the preparation of the food product/intermediate, thus meeting the fourth step in the claims. Moreover, since no starch or protein was removed from the barley, it contains more than at least 10% of the starch and protein associated with the grain, as recited in claim 19. A of anticipation over the cited claims is clearly required.

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Claims 1-3, 9, 11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (U.S. Pat. 5,458,893).

Smith discloses a beta-glucanase-treated glucan for use in a wide variety of edible compositions. See column 8, line 64 through column 9, line 36. The product may be prepared using a variety of sequences of steps, including adding the glucanase and amylase together to cereal flour. See, e.g., Example 4, at columns 11 and 12. Product claims 11 and 14-16 are therefore clearly anticipated by Smith.

With respect to the process claims, Smith clearly provides a food product/intermediate, e.g. oat flour, thereby meeting the second step required in claim 1. Smith mixes the oat flour with beta glucanase and amylase, thereby adding to the food product at least two modifying agents, thus meeting the third step in the claim 1, and the requirements of claim 9. The addition of the glucanase to the oat flour results in obtaining a short chain glucan, thus meeting the first required step in the claims. The addition of the glucanase to the oat flour also results in the preparation of the food product/intermediate, thus meeting the fourth step in the claims. A holding of anticipation over the cited claims is clearly required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (U.S. Pat. 4,871,571).

As discussed above, Jensen discloses a glucanase-digested beta glucan bulking agent from barley, wherein over 80% of the molecular species are from DP₃ to DP₅. See Example 1, at column 8. As also discussed above, Jensen is therefore considered to anticipate many of the claimed embodiments. Jensen differs from the claims under examination in failing to disclose directly the use of glucanase enzymes recited in claims 4 and 5. However, in

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view of Jensen's clear disclosure of the requirement of using beta glucanase enzymes in his process, the selection of known commercially available enzymes such as those recited in claims 4 and 5 must be considered obvious absent some demonstration of an unexpected result coming from their use.

It is also noted that Jensen does not disclose the precise process parameters recited in claim 18. However, Jensen clearly discloses that heat inactivation of the glucanase occurs upon heating to 90 degrees for 20 minutes. Thus, the artisan of ordinary skill, recognizing from Jensen the requirement of heat inactivation, clearly would have been motivated to have performed said inactivation step under any conditions suitable for the inactivation, including those recited in claim 18. Absent some demonstration of an unexpected result, the inactivation step recited in claim 18 must be considered obvious.

Similarly, the determination of suitable protein and starch amounts, recited in claims 19 and 20 must be considered obvious in view of the fact that one of ordinary skill would clearly have recognized that those ingredients would have affected both the physical and nutritional properties of the resulting glucan, and would therefore have been motivated to have optimized those values, depending on the desired properties of the final

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product. Absent some demonstration of an unexpected result, the determination of suitable amounts of protein and starch in glucanase-hydrolyzed cereal flour must be considered a result-effective parameter routinely optimized by the artisan of ordinary skill.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al (U.S. Pat. 3,880,742).

As discussed above, James discloses a process of rendering animal feed more digestible by adding beta glucanase directly, i.e. *in situ*, to barley-based animal feed and is therefore considered to anticipate many of the claimed embodiments. James differs from the claims under examination in failing to disclose directly the use of glucanase enzymes recited in claims 4 and 5. However, in view of James' clear disclosure of the requirement of using beta glucanase enzymes in his process, the selection of known commercially available enzymes such as those recited in claims 4 and 5 must be considered obvious absent some demonstration of an unexpected result coming from their use.

It is also noted that James does not disclose the precise process parameters recited in claim 18. However, Jensen clearly discloses that heat treatment of the thermostable glucanase-containing feed is required for processing. See Example 5, at

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column 9. Thus, the artisan of ordinary skill, recognizing from Jensen the requirement of heat processing, clearly would have been motivated to have performed said processing step under any conditions suitable for said processing, including those recited in claim 18. Absent some demonstration of an unexpected result, the heating step recited in claim 18 must be considered obvious.

James also differs in failing to disclose the production of glucan chains having the claimed molecular weights. However, the molecular weight of the hydrolyzed glucan is a direct function of the degree of hydrolysis of the glucan. Thus, the artisan of ordinary skill practicing James' process clearly would have been motivated to have optimized the degree of hydrolysis so as to optimize the digestibility of the resulting glucan, and thereby obtain a product having the most desirable properties. Therefore, absent some demonstration of an unexpected result, the determination of a suitable molecular weight for the glucan, i.e., a suitable degree of hydrolysis, must be considered obvious in view of the teachings of James.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (U.S. Pat. 5,458,893).

As discussed above, Smith discloses a beta-glucanase-treated glucan for use in a wide variety of edible compositions,

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wherein said product may be prepared using a variety of sequences of steps, including adding the glucanase and amylase together to cereal flour. See, e.g., Example 4, at columns 11 and 12. As also discussed above, Smith is therefore considered to anticipate a number of the claimed embodiments. Smith differs from the claims under examination in failing to disclose directly the use of glucanase enzymes recited in claims 4 and 5. However, in view of Smith's clear disclosure of the requirement of using beta glucanase enzymes in his process, as well as the suitability of Laminex BG (column 4, line 14) the selection of known commercially available enzymes such as those recited in claims 4 and 5 must be considered obvious absent some demonstration of an unexpected result coming from their use.

It is also noted that Smith does not disclose the precise process parameters recited in claim 18. However, Smith clearly discloses that heat inactivation of the glucanase occurs upon heating to 90 degrees for 5 to 45 minutes. See column 7, lines 39-44. Thus, the artisan of ordinary skill, recognizing from Smith the requirement of heat inactivation, clearly would have been motivated to have performed said inactivation step under any conditions suitable for the inactivation, including those recited in claim 18. Absent some demonstration of an unexpected

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result, the inactivation step recited in claim 18 must be considered obvious.

Smith also differs in failing to disclose the production of glucan chains having the claimed molecular weights. However, the molecular weight of the hydrolyzed glucan is a direct function of the degree of hydrolysis of the glucan. Thus, the artisan of ordinary skill practicing Smith's process clearly would have been motivated to have optimized the degree of hydrolysis so as to optimize the beneficial properties of the resulting glucan, and thereby obtain a product having the most desirable properties. Therefore, absent some demonstration of an unexpected result, the determination of a suitable molecular weight for the glucan, i.e., a suitable degree of hydrolysis, must be considered obvious in view of the teachings of Smith. A holding of obviousness over the cited claims is clearly required.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner

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can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP